K073325

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Smith & Nephew, Inc.
Summary of Safety and Effectiveness
Legion Porous Primary Femoral Component

Contact Person and Address
Rishi Sinha
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Smith & Nephew, Inc.
Orthopaedic Reconstruction
1450 Brooks Road
Memphis, TN 38116
(901)399-6054

Date of Summary: 11/19/2007

Name of Device: Legion Porous Primary
Common Name: Knee Prosthesis

DEC 2 0 2007

Device Description

Subject of this premarket notification are the Legion Porous Primary femoral components, which are intended for uncemented applications. The Legion Porous Primary femoral components are offered in cruciate retaining (C/R) and posterior stabilizing (P/S) designs, both manufactured from Cobalt Chrome alloy material. The femoral components are available in sizes 1 through 8 in right and left configurations. The femoral components will porous coated using a -45/+60 titanium bead layer conforming to ASTM F67.

Device Classification

21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis – Class II

Indications for Use

Total Knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are absent or incompetent and the collateral ligaments remain intact. Smith & Nephew Legion Porous Primary femoral components are indicated for use without bone cement and are single use devices.

Substantial Equivalence Information

The overall design of the Legion Porous Primary Femoral Component is based on the existing Genesis II Knee System femoral components cleared under the premarket notifications listed below:

Description	510(K)	Clearance Date
Genesis II Knee System (cemented use)	K951987	8/22/1995
Genesis II Knee System (uncemented use)	K030612	5/27/2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Ms. Rishi Sinha
Regulatory Affairs Specialist
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

DEC 2 0 2007

Re: K073325
Trade/Device Name: Legion Porous Primary Femoral Component
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: November 26, 2007
Received: November 27, 2007

Dear Ms. Sinha:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):
Device Name: Legion Porous Primary Femoral Component

Indications for Use:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchup

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073325